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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,255	02/01/2002	Craig A. Rosen	PZ042P1C1	9759

22195 7590 03/03/2004

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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 03/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/060,255	ROSEN ET AL.	
	Examiner	Art Unit	
	David J Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,11,13,17-20 and 22-46* is/are pending in the application.

4a) Of the above claim(s) *1,2,13,17-20 and 22-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 25-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/03/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] Claims 1-2, 11, 13, 17-20, and 22-46 are pending in the application.

[2] Applicants' amendment to the claims, filed January 20, 2004, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

Election/Restriction

[3] Applicants' election with traverse of the invention of Group II, claims 11 and 25-46 and Group (pp), the polypeptide of SEQ ID NO:52, filed January 20, 2004, is acknowledged. With the regard to the election filed by applicants on October 03, 2003 being non-responsive, applicants argue that they disagree and state that a cursory glance of claims 25-46 as submitted therein would clearly reveal that a single invention was "implicitly" elected, as claims 25-46 are limited to SEQ ID NO:52. Applicants' argument is not found persuasive.

The Office action mailed September 04, 2003 clearly stated that, if the invention of Group II was elected, then a single invention listed as Groups ff) to jjj) was required. However, applicant made no such election, thus rendering the response filed October 03, 2003 non-responsive. While claims 25-46 may be limited to a specific polypeptide sequence, claim 11 is NOT so limited and there is no evidence of record that would indicate that this claim is meant to be so limited. As such, the Office communication mailed December 24, 2003, indicating that Applicants' response filed October 03, 2003 is non-responsive, is proper.

Applicants traverse the restriction requirement in the response filed October 03, 2003 by arguing that a search for the polypeptide of Group II/Group (pp) would overlap with a search of the polynucleotide of Group I, the antibody of Group III, the polypeptide binding partner of Group IV, and the methods of Groups V-X, and therefore, there would be no serious burden on the examiner to co-examine the claims of Groups I-X. Applicants' argument is not found persuasive.

First, it should be noted that MPEP § 803 sets forth two criteria for a proper restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed and (B) There must be a serious burden on the examiner. MPEP § 803 additionally states that a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. The examiner set forth the reasoning as to why the inventions of Groups I-X are independent or distinct (see items [7]-[16] of the Office action mailed September 04, 2003), which is undisputed by applicants, thus satisfying the first criterion for proper restriction. The examiner further set forth the reasoning as to why co-examination of the claims of Groups I-X would require a serious burden (see item [17] of the Office action mailed September 04, 2003). With the exception of Groups II and IV, each of the inventions of Groups I-X has a separate classification and therefore, the co-examination of the claims of Groups II and I, III, and V-X would require a serious burden. Furthermore, even though the inventions of Groups II and IV have the same classification, clearly a search for the polypeptide of Group II would require a search where no pertinent art to the other

subject, *i.e.,* a binding partner, exists. For example, a search of sequence databases and prior art that disclose a polypeptide sequence do not necessarily disclose a binding partner for that polypeptide and as such an additional search for the binding partner for the disclosed polypeptide would be required. Therefore, because the inventions of Groups II and I and III-X have separate classification and/or require a separate patent and non-patent literature and sequence search, a serious burden would be required to co-examine the claims of the elected invention along with the claims of Groups I and III-X. As the two criteria for restriction have been satisfied, the examiner maintains that the requirement is still deemed proper and is therefore made FINAL.

[4] Claims 1-2, 13, 17-20, and 22-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

[5] Claims 11 and 25-46 are being examined on the merits.

[6] Claim 11 is being examined only to the extent the claim reads on the elected subject matter, *i.e.,* Group II/Group (pp).

Information Disclosure Statement

[7] The reference cited on the information disclosure statement (IDS) filed October 03, 2003 has been considered by the examiner. However, in the interest of maintaining confidentiality of unpublished US patent applications, the reference has been lined through on Form PTO-1449. A copy of the IDS is attached to the instant Office action.

Specification/Informalities

[8] Every effort has been made to review the specification for informalities. However, due its sizable length, applicants' cooperation is requested in correcting any errors and/or misspellings that occur in the disclosure.

[9] Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application (09/781,417), specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Priority

[10] Applicant's claim for domestic priority under 35 USC § 119(e) to provisional application 60/149,182, filed August 17, 1999 is acknowledged. Applicant's claim for domestic priority under 35 USC § 120 to US non-provisional applications 09/781,417,

filed February 13, 2001 and PCT/US00/22325, filed August 16, 2000 is acknowledged. The sequence of SEQ ID NO:52 of the instant application is disclosed in provisional application number 60/149,182 as SEQ ID NO:47 and is disclosed in applications 09/781,417 and PCT/US00/22325 as SEQ ID NO:52. Applicant is granted the benefit of the earlier filing date of provisional application 60/149,182 to the extent the priority documents provide support for the claimed subject matter.

Claim Objections

[11] Claim 11 is objected to as being drawn to a non-elected invention. It is suggested that, for example, applicants amend the claim to recite only the elected subject matter of Group II/Group (pp).

[12] Claim 11 is objected to as the claim recites an improper alternative expression. The claim recites the alternative expression "a sequence selected from the group consisting of:"... ..."(h) an allelic variant of SEQ ID NO:Y; or (i) a species homologue of the SEQ ID NO:Y" (underline added for emphasis). It is suggested that, for example, "or" at line 16 of the claim be replaced with "and". See MPEP 2173.05(h) regarding alternative expressions.

[13] Claims 30, 36, 41, and 46 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The

polypeptide of claims 30, 36, 41, and 46 does not further limit the polypeptide of claims 25, 31, 41, and 46, respectively.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

[14] Claims 11 and 25-46 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or well-established utility. The specification asserts the polypeptide of SEQ ID NO:52 has the following utilities: a reagent for differential identification of the tissue(s) or cell type(s) present in a biological sample; treatment and/or diagnosis of diseases and conditions; providing immunological probes for differential identification of tissue(s) or cell type(s); determination of biological activity; as an antigen for raising antibodies; as a tissue marker; the identification of cognate ligands or receptors; identification of reagents that modulate their interactions; as a nutritional supplement; or as a tumor marker and/or immunotherapy targets (see pages 34-36 of the instant specification). However, the asserted utilities of determination of biological activity, as an antigen for raising antibodies, as a tissue marker, the identification of cognate ligands or receptors, and identification of reagents that modulate their interactions are not specific as these utilities apply to the general class of polypeptides. Furthermore, the asserted utilities of a reagent for differential identification of the tissue(s) or cell type(s) present in a

biological sample, treatment and/or diagnosis of diseases and conditions, providing immunological probes for differential identification of tissue(s) or cell type(s), a nutritional supplement, and a tumor marker and/or immunotherapy targets are not substantial as further research is clearly required to identify a "real world" use for the claimed polypeptide due to the failure of the specification for providing the necessary guidance for using the claimed polypeptide for differential identification, disease treatment and/or diagnosis, as a nutritional supplement, or as a disease marker. For example, none of the necessary information regarding identification and statistically relevant use of a potential disease marker as suggested by Hammond et al. (*Semin Oncol* 29:213-221) has been provided in the specification. Thus, in view of the failure of the specification to provide the guidance necessary for using the claimed polypeptide for using the claimed polypeptide for differential identification, disease treatment and/or diagnosis, as a nutritional supplement, or as a disease marker, further experimentation is clearly required to identify a real-world use for the claimed polypeptide. This type of utility is not considered a "substantial utility". See e.g., *Brenner v. Manson,* 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). The specification must teach a skilled artisan how to use what is claimed and not merely provide a blueprint for further experimentation in order for an artisan to identify a use for the claimed invention. As stated in *Brenner v. Manson*, 383 U.S. 519 535-536, 148 USPQ 689, 696 (1966), "[a] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion". Here the specification fails to provide a specific benefit in currently available form for the claimed polypeptide.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[15] Claim(s) 11, 26, 30-31, 34-36, 41, and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

[16] Claim 11 is indefinite in the recitation of "biological activity". The term "biological activity" is not defined by the claim nor the specification and the meaning of this term is unclear. It is suggested that the term "biological activity" be replaced with a term that clearly defines applicants' intended biological function.

[17] Claims 11 and 31 (claims 34-36 dependent therefrom) are indefinite in the recitation of "a secreted form" (claim 11) and "the secreted portion". While it is noted that the specification identifies the first amino acid of the secreted portion of the polypeptide of SEQ ID NO:52/the polypeptide encoded by HCDBP36 cDNA as being amino acid 22 (see Table 1, page 73 of the instant specification), it is unclear as to the whether a "secreted form" or a "secreted portion" is meant to be interpreted as amino acids 22-85 of SEQ ID NO:52, or some other range of amino acids. As such, it is unclear as to the scope of claimed polypeptides. It is suggested that applicants clarify the meaning of the terms.

[18] Claim 26 is indefinite in the recitation of "[t]he isolated protein of 25". It appears that applicants intend for the claim to recite "[t]he isolated protein of claim 25" and claim 26 has been examined accordingly. It is suggested that applicants clarify the claim.

[19] Claims 30, 36, 41, and 46 are rejected as being unclear as to the scope of claimed isolated proteins. The claims are drawn to an isolated protein produced by expressing a protein of claim 25, 31, 37, or 42, respectively, and recovering said protein. Although the cell expresses the protein of claim 25, 31, 37, or 42, it is unclear as to whether the recovered protein is the protein of claim 25, 31, 37, or 42, or some other protein produced by the cell. It is suggested that applicants clarify the meaning of the claims.

[20] Claim 31 recites the limitation "the secreted portion". There is insufficient antecedent basis for this limitation in the claim. It is suggested that applicants correct antecedent basis in the claim.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

[21] Claims 26 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of he claimed invention. This is a new matter rejection. The examiner can find no support in the specification or claims (there appear to be no drawings present in the instant application) as originally filed for a polypeptide comprising the range of amino acids of 2 to 85 of SEQ ID NO:52 (claim 26) or a polypeptide comprising the polypeptide encoded by the HCDP36 cDNA contained in ATCC Deposit No. PTA-499, excepting the N-terminal methionine. Applicants are invited to direct the examiner's attention to such support. Absent such support, these limitations are considered to be new matter.

[22] Claims 11, 25, 28-31, and 34-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of he claimed invention.

The claims are drawn to a genus of isolated proteins comprising variants and fragments of SEQ ID NO:52 or the polypeptide encoded by the HCDBP36 cDNA contained in ATCC Deposit No. PTA-499. For claims drawn to a genus, MPEP § 2163 states the written description requirement for a claimed genus may be satisfied through sufficient description of a *representative number of species* by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a

combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The specification discloses only a SINGLE representative species of the claimed genus of polypeptides, *i.e.*, SEQ ID NO:52. The specification fails to describe any additional representative species of the claimed genus. While MPEP § 2163 acknowledges that in certain situations "one species adequately supports a genus", it is also acknowledges that "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus". In the instant case, the claimed genus of polypeptides encompasses species that are widely variant in both structure and function, including (but not limited to) polypeptides having ANY function including non-functional polypeptides. As such, the disclosure of the single representative species of SEQ ID NO:52 is insufficient to be representative of the attributes and features of *all* species encompassed by the claimed genus of polypeptides. Given the lack of description of a representative number of polynucleotides, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

[23] Claims 11 and 25-46 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

[24] Even if the polypeptide of SEQ ID NO:52 is found to have patentable utility, the following rejection still applies: claim(s) 11, 25, 28-31, and 34-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated polypeptide of SEQ ID NO:52, does not reasonably provide enablement for all polypeptides comprising variants and fragments of SEQ ID NO:52 or variants and fragments of the polypeptide encoded by the HCDBP36 cDNA contained in ATCC Deposit No. PTA-499 as broadly encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

It is the examiner's position that undue experimentation would be required for a skilled artisan to make and/or use the entire scope of the claimed invention. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)) as follows: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to

make or use the invention based on the content of the disclosure. See MPEP § 2164.01(a). The Factors most relevant to the instant rejection are addressed in detail below.

- The claims are overly broad in scope: The claims are so broad as to encompass a vast number of polypeptides comprising variants and fragments of SEQ ID NO:52 or variants and fragments of the polypeptide encoded by the HCDBP36 cDNA contained in ATCC Deposit No. PTA-499. The broad scope of claimed polypeptides is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides having any function broadly encompassed by the claims. In this case the disclosure is limited to the isolated polypeptide of SEQ ID NO:52.

- The lack of guidance and working examples: The specification provides only a single working example of the claimed polypeptides, *i.e.,* SEQ ID NO:52. This working example fails to provide the necessary guidance for making and/or using the entire scope of claimed polypeptides. The specification fails to provide guidance regarding those amino acids of SEQ ID NO:52 that may be altered by substitution, addition, insertion, and/or deletion with an expectation of maintaining the desired biological activity. Furthermore, the specification fails to provide guidance as to how to use those variant polypeptides having an activity other than the activity of SEQ ID NO:52, *e.g.*, non-functional polypeptides.

- The high level of unpredictability in the art: The amino acid sequence of a polypeptide determines its structural and functional properties. Predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e., expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. The positions within a protein's amino acid where modifications can be made with a reasonable expectation of success in obtaining a polypeptide having the desired activity/utility are limited and the result of such modification(s) is HIGHLY unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, *e.g.,* multiple substitutions. In this case, the necessary guidance has not been provided in the specification as explained in detail above.

- The state of the prior art supports the high degree of unpredictability: The state of the art provides evidence for the high degree of unpredictability in altering a polypeptide sequence with an expectation that the polypeptide will maintain the desired activity/utility. For example, Branden et al. ("Introduction to Protein Structure", Garland Publishing Inc., New York, 1991) teach "[p]rotein engineers frequently have been surprised by the range of effects caused by single mutations that they hoped would change only one specific and simple property in enzymes" and "[t]he often surprising results of such experiments reveal how little we know about the rules of protein stability... ...they also serve to emphasize how difficult it is to design *de novo* stable

proteins with specific functions" (page 247). While it is acknowledged that this reference was published in 1991, to date there remains no method for reasonably predicting the effects of even a single amino acid mutation on the biological activity of a protein.

- The amount of experimentation required is undue: While methods of generating variants of a given polypeptide are known, e.g., by site-directed or random mutagenesis of the encoding polynucleotide, it is not routine in the art to screen for all polypeptide variants and fragments having a substantial number of modifications as encompassed by the instant claims. In view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, and the high degree of unpredictability as evidenced by the prior art, undue experimentation is necessary for a skilled artisan to make and use the entire scope of the claimed invention.

Thus, applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

[25] Claims 11, 31-36, and 42-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one

skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a host cell comprising a novel vector, i.e., ATCC Deposit No. PTA-499. Since the vector is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The vector's sequence is not fully disclosed, nor has all the sequences required for its construction been shown to be publicly known and freely available. The enablement requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the vector. The specification does not disclose a repeatable process to obtain the vector and it is not apparent if the vector sequence is readily available to the public. Accordingly, it is deemed that a deposit of this vector should have been made in accordance with 37 CFR 1.801-1.809.

It is noted that applicants have assigned an ATCC deposit number to the host cell comprising the novel vector. However, there is no indication in the specification as to public availability. If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants

may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

1. during the pendency of this application , access to the invention will be afforded to the Commissioner upon request;

2. all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

3. the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

4. the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

[26] Claim(s) 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Database EMBL Accession Number S28381 (see Appendix A). The claim is drawn to (in relevant part) an isolated polypeptide comprising an amino acid sequence at least 95% identical to a fragment of SEQ ID NO:52 optionally having biological activity, a polypeptide

domain of SEQ ID NO:52, or an epitope of SEQ ID NO:52. Database EMBL Accession Number S28381 teaches a polypeptide comprising an amino acid sequence that is 100% identical to amino acids 35-41 of SEQ ID NO:52. This anticipates claim 11 as written.

Conclusion

[27] Status of the claims:

- Claims 1-2, 11, 13, 17-20, and 22-46 are pending.
- Claims 1-2, 13, 17-20, and 22-24 are withdrawn from consideration.
- Claims 11 and 25-46 are rejected.
- No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652
03-01-04

APPENDIX A

```
S28381
utrophin - human
N;Alternate names: dystrophin-related protein
C;Species: Homo sapiens (man)
C;Date: 17-Apr-1993 #sequence_revision 03-Oct-1995 #text_change 16-Jul-1999
C;Accession: S28381; S28914; S03966
R;Tinsley, J.M.
submitted to the EMBL Data Library, November 1992
A;Reference number: S28381
A;Accession: S28381
A;Molecule type: mRNA
A;Residues: 1-3433 <TIN1>
A;Cross-references: EMBL:X69086; NID:g34811; PIDN:CAA48829.1; PID:g34812
R;Tinsley, J.M.; Blake, D.J.; Roche, A.; Fairbrother, U.; Riss, J.; Byth, B.C.; Knight, A.E.;
Kendrick-Jones, J.; Suthers, G.K.; Love, D.R.; Edwards, Y.H.; Davies, K.E.
Nature 360, 591-593, 1992
A;Title: Primary structure of dystrophin-related protein.
A;Reference number: S28914; MUID:93096045; PMID:1461283
A;Accession: S28914
A;Molecule type: mRNA
A;Residues: 27-246;2839-3343 <TIN2>
A;Cross-references: EMBL:X69086
R;Love, D.R.; Hill, D.F.; Dickson, G.; Spurr, N.K.; Byth, B.C.; Marsden, R.F.; Walsh, F.S.;
Edwards, Y.H.; Davies, K.E.
Nature 339, 55-58, 1989
A;Title: An autosomal transcript in skeletal muscle with homology to dystrophin.
A;Reference number: S03966; MUID:89238543; PMID:2541343
A;Accession: S03966
A;Molecule type: mRNA
A;Residues: 2944-3433 <LOV>
A;Cross-references: EMBL:X15488; NID:g30933; PIDN:CAA33515.1; PID:g930062
C;Comment: This protein is found primarily at the neuromuscular junctions in adult muscle. In
patients with Duchenne muscular dystrophy, it is also found in the sarcolemma. It also occurs in
fetal and regenerating muscle.
C;Genetics:
A;Gene: GDB:UTRN; DMDL
A;Cross-references: GDB:119851; OMIM:128240
A;Map position: 6q24-6q24
C;Superfamily: dystrophin; alpha-actinin actin-binding domain homology; spectrin/dystrophin
repeat homology; WW repeat homology
C;Keywords: actin binding; cytoskeleton; leucine zipper; membrane-associated protein; muscle;
neuromuscular junction; structural protein; tandem repeat; triple helix
F;30-248/Domain: alpha-actinin actin-binding domain homology <ACT>
F;308-417/Domain: spectrin/dystrophin repeat homology <SP01>
F;418-526/Domain: spectrin/dystrophin repeat homology <SP02>
F;528-637/Domain: spectrin/dystrophin repeat homology <SP03>
F;638-685/Region: hinge
F;686-796/Domain: spectrin/dystrophin repeat homology <SP04>
F;804-902/Domain: spectrin/dystrophin repeat homology <SP05>
F;906-1013/Domain: spectrin/dystrophin repeat homology <SP06>
F;1015-1122/Domain: spectrin/dystrophin repeat homology <SP07>
F;1124-1230/Domain: spectrin/dystrophin repeat homology <SP08>
F;1232-1334/Domain: spectrin/dystrophin repeat homology <SP09>
F;1339-1450/Domain: spectrin/dystrophin repeat homology <SP10>
F;1451-1541/Domain: spectrin/dystrophin repeat homology #status atypical <SP11>
F;1543-1649/Domain: spectrin/dystrophin repeat homology <SP12>
F;1651-1755/Domain: spectrin/dystrophin repeat homology <SP13>
F;1856-1973/Domain: spectrin/dystrophin repeat homology <SP14>
F;1975-2081/Domain: spectrin/dystrophin repeat homology <SP15>
F;2083-2185/Domain: spectrin/dystrophin repeat homology <SP16>
F;2227-2333/Domain: spectrin/dystrophin repeat homology <SP17>
F;2335-2440/Domain: spectrin/dystrophin repeat homology <SP18>
F;2442-2556/Domain: spectrin/dystrophin repeat homology <SP19>
F;2558-2688/Domain: spectrin/dystrophin repeat homology <SP20>
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F;2690-2797/Domain: spectrin/dystrophin repeat homology <SP21>
F;2798-2869/Region: hinge
F;2812-2849/Domain: WW repeat homology <WW1>
F;2837-3117/Region: cysteine-rich
F;3263-3284/Region: leucine zipper motif
F;3328-3349/Region: leucine zipper motif

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  Best Local Similarity   100.0%;  Pred. No. 63;
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Qy         35 LERKIQL 41
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Db        790 LERKIQL 796
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